

Translation of the decision from AFSSAPS dated March 08, 2006

AFSSAPS (Agence française de sécurité sanitaire des produits de santé – French drugs security Administration).

Decision dated March 08, 2006, concerning the prohibition of the manufacturing, conditioning, importation, supplying, putting on the market for free or against payment, possession aimed at selling or supplying for free or against payment, and the use of cosmetic products containing vitamin K1 (INCI name : Phytonadione)

The Chairman of the Afssaps,

Having regard to the European Communities Council directive 76/768/EEC of 27 July 1976 amended concerning the harmonization of Member States legislations with respect to cosmetic products , and in particular its article 12;

Having regard to the Code of Public Health, and in particular its articles L.5131-1, L.5131-4, L.5131-6, L.5131-9, L.5311-1, L.5312-1 and L.5312-3;

Having regard to the five adverse effects of allergic nature reported to the Afssaps between December 2003 and June 2004, resulting from the use of three cosmetic products containing vitamin K1 and leading, on the one hand, to the stopping of their commercialization as of 12 November 2004 and, on the other hand, to the callback of the concerned batches upon request of the AFSSAPS as well as to the posting of an alert message on its website on 10 January 2005;

Having regard to the serious adverse effect reported to the Afssaps between February 2006, resulting from the use of a cosmetic products containing vitamin K1, leading to the callback of concerned batches following the above-mentioned warning message but the purchasing of which was made before this callback;

Having regard to the six adverse effects of allergic nature reported to the Afssaps between March 2004 and July 2004, resulting from the use of another cosmetic product containing vitamin K1 and leading, on the one hand, to the stopping of their commercialization as of 29 June 2004 and, on the other hand, to the callback of the

concerned batches upon request of the Afssaps as well as to the posting of an alert message on its website on 10 January 2005;

Having regard to the new data originating from the scientific literature published between February and September 2005 reporting two cases of induction of sensitization to vitamin K1 by topical means in Spain and in Italy, resulting from the use of cosmetic products containing that ingredient;

Having regard to the opinion of the commission of cosmetology dated 29 September 2005 and 16 February 2006;

Having regard to the communications dated 12 January 2006 addressed to the representatives of the cosmetic industry and notifying them a draft decision of the AFSSAPS relating to the prohibition of the manufacturing, conditioning, importation, supplying, putting on the market for free or against payment, possession aimed at selling or supplying for free or against payment, and the use of cosmetic products containing vitamin K1 (INCI name : Phytanadione);

Having regard to the communications dated 30 January and 2 February 2006 of the representatives of the cosmetic industry in response to the present draft decision;

Whereas a cosmetic product put into market shall not be harmful to human health;

Whereas the twelve adverse effects reported to the Afssaps and resulting from the use of the above-mentioned cosmetic products consisted in contact eczemas of the face or the body; whereas six of this effects, considered as serious, respectively led to one hospitalization, two social discomforts and three generalized eczemas;

Whereas the above-mentioned twelve adverse effects , and the two cases reported in the scientific publications, are of allergic nature, regardless of the dose, and result in induction of sensitization with break of immune tolerance vis-à-vis vitamin K1;

Whereas the induction of this sensitization does permanently not allow the sensitized subjects to make use of vitamin K1 without any risk, except being exposed to systemic reactions of the generalized eczemas type, in case of therapeutic use by means of

injection of this ingredient in the treatment of hemorrhagic diseases linked to a deficiency of vitamin K1 or to over dosages of anticoagulants;

Whereas, in consequence, cosmetic products containing vitamin K1 present a serious danger to human health;

Whereas cosmetic products based on vitamin K1 may currently potentially be commercialized;

Decides:

Article 1: The manufacturing, conditioning, importation, supplying, putting on the market for free or against payment, possession aimed at selling or supplying for free or against payment, and the use of cosmetic products containing vitamin K1 (INCI name : Phytonadione; CAS #: 84-80-0) is temporarily prohibited, as conservative measure, as from the publication of the present decision and awaiting, either appropriate measures taken by the European Commission in compliance with the provisions of Article 12 paragraph 2 of the above-mentioned directive 76/768/EEC, or the entry into force, if any, of the technical adjustments to this directive taken in compliance with the provisions of its Article 12 paragraph 3.

Article 2: Those who manufacture, import, who are responsible for the putting on the market and supply cosmetic products containing vitamin K1 shall take all necessary steps, in particular towards stocks holders, to have bulk or retail supply of these products stopped at any place where they can be found and to proceed to their withdrawal once the present decision has been published.

Article 3: The director of the appraisal of advertising, cosmetic products and biocides and the director of the inspection and the institutions are, as far as they are concerned, each in charge of the execution of the present decision, which will be published in the Official Journal of the French Republic.

Done at Saint Denis, on March 08, 2006

The Chairman

Jean MARIMBERT